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05/15/2006

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EXAMINER

STANDLEY, STEVEN H

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Response to Amendment

The amendment filed 3/03/06 has been made of record. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Objections/Rejections: Withdrawn

Claim Objections

Objection to claim 78 is withdrawn due to applicant's cancellation of the claim.

ODP

Rejection of claims 41-42, 45, 47-48, 71-72, 75, 77, and 78 as obvious double-patenting is withdrawn due to applicant's cancellation of claims 47, 77 and 78, amendment to a method of treating a patient suffering from Parkinson's disease now recited in the independent claim 41.

Claim Rejections - 35 USC § 112

Rejection of claims 44-46, 48, 53-55, 71-76, and 78-80 under 35 USC § 112, 1st paragraph, enablement related specifically to claims encompassing numerous diseases is withdrawn due to applicant's amendment to Parkinson's disease.

Objections/Rejections: Maintained/New Grounds

Claim Rejections - 35 USC § 112

Rejection of claims 41-46, 48, and 50-55 under 35 USC § 112, 1st paragraph, enablement is maintained for the reasons made of record in the office action dated 10/07/05. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that "the possibility that the methods may not achieve a total cure or prevention is not detrimental to enablement and need not be excluded from the claims. Enablement does not require that the generic claims function in every conceivable circumstance."

On the contrary, Applicant's arguments are not persuasive because applicant's invention does not teach even one circumstance claimed. There are no examples of curing or preventing and no apparent circumstances wherein any animal is cured or the entire pathology of the disease is prevented.

Claim Rejections - 35 USC § 102

Rejection of claims 41, 42, 44, 45, 46, 48, 50, 51-55, 71, 72 74, 75 and 76, and 80-84 under 35 USC § 102(e) over Jensen is maintained for the reasons made of record in the office action dated 10/07/05. Applicant's arguments have been fully considered and not found to be persuasive. Applicant makes the unsupported assertion that Jensen does not teach administration of A-beta for the treatment of Parkinson's. Further, applicant attempts to characterize the Jensen's intentions without any supporting language from Jensen et al, stating "insofar as one can determine what Jensen is proposing, it would appear more likely he is proposing that other diseases be treated not with A beta, *the*

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major peptide associated with Alzheimer's disease, but with whatever peptide plays a comparable role in the disease in question [page 15, Remarks, emphasis added].” The logic of the previous statement is that one of skill in the art would ***not*** administer a-beta to a Parkinson's patient because a-beta is not an amyloidogenic protein in Parkinson's disease. The examiner notes that nowhere in the Jensen patent application is applicant's interpretation supported. Furthermore, one of skill in the art at the time of Jensen knows that a-beta deposits are present in the brains of patient's with Parkinson's disease as well as Alzheimer's disease (see evidence below). Thus, one of skill in the art would have clearly understood the value of the combination of treating Parkinson's by administration of a-beta as claimed by Jensen because Jensen treats a patient population with amyloidogenic disease that comprises plaques containing a-beta which is reasonably Parkinson's disease as well as Alzheimer's.

Claim Rejections - 35 USC § 103

Rejection of claims 41, 43-46, 48, 50-55, 71, 73-76, 78-80 and 80-84 under 35 USC § 103(a) is maintained for the reasons made of record in the office action dated 10/07/06. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues as above and further requests reconsideration of claims 54, 55, and 81-84. Jensen recites prevention throughout, and notably in 'field of invention' wherein prevention is of AD is disclosed. The only rationale way to prevent AD is to administer to a patient that currently does not have the disease. Therefore Jensen clearly contemplates the limitations of said claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Primavera et al (1999) is a Harvard study of the distribution of amyloid a-beta in neurodegenerative diseases other than Alzheimer's disease. Figure 4 (page 188) clearly shows that a-beta plaques are present in Parkinson's patients (see 'PD' at bottom and compare to control levels). Clearly a-beta containing amyloid deposits are greater in abundance in PD than in age-matched control patients.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven H. Standley whose telephone number is (571) 272-3432. The examiner can normally be reached on 8:00-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Janet Andre can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Steven Standley, Ph.D.

7/24/05 SJS/06


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER